TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
B14485.3 LP		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/FR2004/050602	19.11.2004	27.11.2003

International Patent Classification (IPC) or national classification and IPC

A61M5/142, A61N1/05, B81C1/00

Applicant

COMMISSARIAT A L'ENERGIE ATOMIQUE

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 5 sheets, as follows:

      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

☐ the international application as originally filed/furnished

☒ the description:

pages 1-22 as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* 1-23 received by this Authority on 05.08.2005 with letter of 29.07.2005

nos.* _____ received by this Authority on _____

☒ the drawings:

sheets 1/10-10/10 as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	14, 16	YES
	Claims	1-13, 15, 17-23	NO
Inventive step (IS)	Claims		YES
	Claims	1-23	NO
Industrial applicability (IA)	Claims	1-23	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

1. Reference is made to the following documents:
D1: WO 0243937
D2: WO 0218785
D3: US 2002198512
D4: US 2002193818
D5: WO 0134088

Novelty (PCT Article 33(2))

2. The present application fails to meet the requirements of PCT Article 33(1), since the subject matter of **claims 1 to 13, 15 and 17 to 23** appears not to comply with the criterion of novelty as defined by PCT Article 33(2).

2.1 D1 describes a microdevice for *in vivo* diagnosis or therapy (figures 11 to 21), which includes:

claim 1:
- a body having a substantially longitudinal shape and a quadrilateral cross-section, provided along its length with at least one main channel (1602, 1911) of which one inlet is at a first end of said body;
- one or more secondary channels (channels perpendicular to 1602) connected to said at least one main channel via lateral outlets;

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

claims 2 & 3: - one or more electrodes (1905) located on an external portion of the body;
- one or more electrical connection pads located on the first end of the body;

claims 4 & 5: - micro-indentations (figure 19b) having a height and width between 10 microns and 50 microns (page 2, last paragraph).

Claims 6 to 7 & 13: - said microdevice further comprises at least two channels (1602);
- and two parallel surfaces.

Claims 9 to 12: - said cross-section has a maximum size of less than 1 mm or 300 µm, is rectangular and the body has a longitudinal extension between 0.5 and 3 cm.

Claim 15: - the microdevice is made of silicon.

Claims 17 to 23: - method for producing a diagnostic microdevice (since the microdevice of claim 1 is not novel, the production method is not novel either).

According to the applicant, D1 does not describe an implantable device.

However, on page 33, lines 4 and 5, D1 describes a microneedle. Said microneedle is partially implanted in the human body during diagnosis or therapy and can therefore be considered to be *in vivo*.

The feature of the device being implantable is not mentioned as such in the claims. The claims mention an *in vivo* microdevice, which does not necessarily mean that the microdevice is totally implanted or totally *in vivo*.

Consequently, D1 describes a microdevice for diagnosis or therapy, according to claims 1 to 7, 9, 12 to 13, 15 and 17 to 23.

2.2 D2 describes a microdevice for *in vivo* diagnosis or therapy (figures 1 to 87), which includes:

claims 1-13, 15:

- a body having a substantially longitudinal shape and a quadrilateral cross-section (6), provided with at least one main channel (20) along its length (figures 1 to 87);
- one or more secondary channels (figure 2) connected to at least one main channel (20) by lateral outlets;
- electrodes (page 11, line 7 to line 15);
- a silicon material (see page 38, claim 16).

According to the applicant, D2 does not describe an implantable device.

However, on page 10, line 27 to page 11, line 15, D2 describes a microdevice of which a portion of the electrode or of the microdevice is implanted in the human body. Said microdevice can be an electrode joined to a dermal patch. Consequently, D2 describes the technical features of claims 1 to 13 and 15.

2.3 D3 to D5 also describe the features of claims 1 to 3 and 8 to 12.

D3: - an *in vivo* microdevice (paragraph 45 "tissue penetrating shaft"; here it is clear that the microdevice is capable of being inside the human body) including at least one main channel (10c) (figures 1 to 13), a plurality of secondary channels (10d), electrodes (25) and conductors (26);

D4: - an *in vivo* microdevice ("microneedle (10)"; a microneedle may be considered to be an *in vivo*

microdevice) including at least one main channel (64) (figures 1 to 3 and 6), a plurality of secondary channels (20, 22), electrodes (28) and silicon (paragraph 18, use of SOI).

D5: - an *in vivo* microdevice (figure 1 shows an electrode (72) in a catheter (38), which is capable of being *in vivo* or implanted) having connection pads (74).

Inventive step (PCT Article 33(3))

3. The present application fails to meet the requirements of PCT Article 33(1), since the subject matter of **claims 14 and 16** does not appear to involve an inventive step as defined by PCT Article 33(3). Slight alterations to the construction of the microdevice (funnel shape, wave-guide) described in claim 3 are defined in claims 14 and 16. Said alterations are part of the standard practice of a person skilled in the art and the resulting advantages are easily foreseeable. Consequently, the subject matter of said claims does not appear to involve an inventive step.

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Box No. VII **Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

1. Contrary to the requirement of PCT Rule 5.1(a)(ii), the relevant prior art disclosed in **D1 to D4** has not been indicated in the description, nor have said documents been cited.

2. Independent claims 1 and 17 have not been drafted in two parts, as required by PCT Rule 6.3(b), yet such a drafting would appear to be appropriate in this particular case, with a preamble containing the combination of features known from the prior art (D1) (PCT Rule 6.3(b)(i)), and a characterising part containing the remaining features (PCT Rule 6.3(b)(ii)).

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Although claims 1 and 3 have been drafted as separate independent claims, it appears that they have the same subject matter and that they differ only by virtue of a variation in the definition of the subject matter for which protection is sought.
Consequently, said claims are not concise and fail to meet the requirements of PCT Article 6.